

least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the carton label and on the above-mentioned leaflet accompanying the article contained in the cases and in the cartons were false and misleading. The statements represented and suggested that the article in the cases and cartons was an adequate and effective treatment for gastric and duodenal ulcers and would completely heal ulcer craters.

Further misbranding, Section 502 (f) (1), the labeling of the repackaged article contained in the cartons failed to bear adequate directions for use since the directions on the carton "Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing" were not adequate directions for use in the treatment of gastric and duodenal ulcers.

The article contained in the cases and as repackaged in the cartons was misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** May 26, 1954. Torbert Laboratories, Inc., New Rochelle, N. Y., claimaint, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for the destruction of the labeled cartons and leaflets and the relabeling of the product under the supervision of the Food and Drug Administration.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

4351. Adulteration of oxygen. U. S. v. John Suydam (Newburgh Oxygen Co.), and George H. Gordon. Pleas of guilty. Fine of \$750 against Defendant Suydam and \$150 against Defendant Gordon. Jail sentence of 6 months against Defendant Suydam suspended and defendant placed on probation for 6 months; jail sentence of 3 months against Defendant Gordon also suspended and this defendant placed on probation for 3 months. (F. D. C. No. 30044. Sample Nos. 73341-K, 73343-K, 74527-K.)

**INFORMATION FILED:** February 7, 1952, Southern District of New York, against John Suydam, trading as the Newburgh Oxygen Co., Newburgh, N. Y., and George H. Gordon, an employee in the business.

**ALLEGED VIOLATION:** At a time prior to April 25, 1950, while a large metal cylinder of carbon dioxide was being held for sale at the Newburgh Oxygen Co., after shipment in interstate commerce, the defendants repacked a quantity of the carbon dioxide into a small metal cylinder and attached to the cylinder a tag containing the printed and graphic matter set forth below; and, on or about April 25, 1950, the defendants sold and delivered the small metal cylinder containing carbon dioxide, and in the invoice of such sale, represented that this metal cylinder contained *oxygen*. It was alleged that such acts of repacking and labeling of the article in the small metal cylinder resulted in the article in the small cylinder being adulterated.

**LABEL, IN PART:** (Tag) "Newburgh Oxygen Co. Newburgh, N. Y. Phone 2745  
Carbon Dioxide—% Oxygen Only—% Cyl. No.— Filled 4/25/50 Empty  
—Tear Off here when empty Full."

**NATURE OF CHARGE:** Adulteration, Section 501 (d) (2), carbon dioxide had been substituted for *oxygen*, which the article was represented to be.

**DISPOSITION:** April 29, 1954. The defendants having entered pleas of guilty, the court fined Defendant Suydam \$750 and Defendant Gordon \$150. Defendant Suydam also was sentenced to 6 months in jail and Defendant Gordon to 3 months, but both jail sentences were suspended and Defendant Suydam was placed on probation for 6 months and Defendant Gordon for 3 months.

**4352. Adulteration and misbranding of Neo-Lifo B-12 and Livo-12-Crude.** U. S. v. American Bio-Chemical Corp., Abraham Rothenberg, and Vincent M. Leuterio (indictment). U. S. v. Al G. Johns (information). Pleas of guilty. Fine of \$400 against corporation and \$50 against each individual. (F. D. C. No. 33769. Sample Nos. 33249-L, 42312-L, 53016-L.)

**INDICTMENT RETURNED:** Between August 12 and October 1, 1953, Southern District of California, against the American Bio-Chemical Corp., Los Angeles, Calif., Abraham Rothenberg, production manager of the corporation, and Vincent M. Leuterio, bacteriologist of the corporation.

**INFORMATION FILED:** December 14, 1953, Southern District of California, against Al G. Johns, president and treasurer of the American Bio-Chemical Corp.

**ALLEGED VIOLATION:** On or about July 3 and 14, 1952, the defendant corporation and each of the individual defendants caused to be introduced into interstate commerce, at Los Angeles, Calif., for delivery to Detroit, Mich., and Herrin, Ill., a quantity of *Neo-Lifo B-12* which was adulterated and misbranded.

In addition, the defendant corporation and Defendant Rothenberg and Defendant Leuterio, on or about May 14, 1952, gave to a firm engaged in the business of shipping drugs in interstate commerce, at Palo Alto, Calif., an invoice containing a guaranty which provided that the *Livo-12-Crude* listed in the invoice was neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. On or about May 14, 1952, the defendant corporation and Defendant Rothenberg and Defendant Leuterio delivered to the holder of the guaranty, at Palo Alto, Calif., a quantity of *Livo-12-Crude* which was adulterated and misbranded.

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the quality and purity of the articles fell below that which they were represented to possess. The articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms.

Misbranding, section 502 (a), the label statement "Sterile Solution" appearing on the label of each of the articles was false and misleading since the articles were not sterile solutions but were solutions contaminated with viable micro-organisms.

**DISPOSITION:** January 4, 1954. The defendants having entered pleas of guilty, the court fined the corporation \$400 and each individual defendant \$50.

**4353. Adulteration and misbranding of digitoxin tablets.** U. S. v. 36 Bottles \* \* \*. (F. D. C. No. 36225. Sample No. 39649-L.)

**LIBEL FILED:** January 7, 1954, Southern District of California.

**ALLEGED SHIPMENT:** On or about September 28, 1953, by Richlyn Laboratories, from Philadelphia, Pa.

**PRODUCT:** 36 1,000-tablet bottles of *digitoxin tablets* at Los Angeles, Calif. Examination showed that the product contained 0.15 mg. of cardioactive gly-